

EPA Registration Number 2517-166 Volume 2

PROCESSING REQUEST

Reg #: 2517-166

Decision #: 496680

Description: label amendment

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated: 4-3-15

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐ Notification Dated:

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Maggie Rudick

Division: RD/IVB1

Phone: 703-347-0257

Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 3, 2015

Prince Bamaze
Sergeant's Pet Care Products, Inc.
10077 S. 134th St.
Omaha, NE 68138

Subject: Label Amendment – Add Marketing Statements and Alternate Brand Names
Product Name: SPCP4
EPA Registration Number: 2517-166
Application Date: January 22, 2015
Decision Number: 496680

Dear Mr. Bamaze:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 2517-166
Decision No. 496680

with FIFRA section 6. If you have any questions, please contact Maggie Rudick by phone at 703-347-0257, or via email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', with a large, sweeping flourish extending to the right.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 1 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

SPCP4 (DOG)

Editor's Note: [Optional proposed text appears in brackets – the final label may include some or all of the optional text]

SPCP4

{ABN} [Sergeant's Deltamethrin Collar]
{ABN} [Bansect Flea & Tick Collar for Dogs]
{ABN} [Bansect III Flea & Tick Collar for Dogs]
{ABN} [Bansect 3 Flea & Tick Collar for Dogs]
{ABN} [Sergeant's Triple Protection Flea & Tick Collar]
{ABN} [Sergeant's Dual Action Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [Sergeant's Dual Action Flea & Tick Collar for Dogs]
{ABN} [Sergeant's Dual Action Flea & Tick Collar for Large Dogs]
{ABN} [Sergeant's Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [Sergeant's III Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [Sergeant's 3 Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [Sergeant's Flea & Tick Collar for Dogs]
{ABN} [Sergeant's III Flea & Tick Collar for Dogs]
{ABN} [Sergeant's 3 Flea & Tick Collar for Dogs]
{ABN} [Sergeant's Flea & Tick Collar for Large Dogs]
{ABN} [Sergeant's III Flea & Tick Collar for Large Dogs]
{ABN} [Sergeant's 3 Flea & Tick Collar for Large Dogs]
{ABN} [Sergeant's Silver Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [Sergeant's Silver Flea & Tick Collar for Dogs]
{ABN} [Sergeant's Silver Flea & Tick Collar for Large Dogs]
{ABN} [SENTRY Dual Action Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [SENTRY Dual Action Flea & Tick Collar for Dogs]
{ABN} [SENTRY Dual Action Flea & Tick Collar for Dogs and Puppies]
{ABN} [SENTRY Dual Action Flea & Tick Collar for Large Dogs]
{ABN} [SENTRY Flea & Tick Collar for Dogs]
{ABN} [SENTRY Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [SENTRY Flea & Tick Collar for Dogs]
{ABN} [SENTRY Flea & Tick Collar for Large Dogs]
{ABN} [SENTRY Flea & Tick Collar for Dogs & Puppies]
{ABN} PetArmor® Collar for Dogs
{ABN} PetArmor® Collar for Small Dogs
{ABN} PetArmor® Collar for Small Dogs and Puppies
{ABN} PetArmor® Collar for Dogs and Puppies
{ABN} PetArmor® Collar for Medium Dogs
{ABN} PetArmor® Collar for Large Dogs
{ABN} PetArmor® Flea and Tick Collar for Dogs
{ABN} PetArmor® Flea and Tick Collar for Small Dogs
{ABN} PetArmor® Flea and Tick Collar for Small Dogs and Puppies
{ABN} PetArmor® Flea and Tick Collar for Dogs and Puppies
{ABN} PetArmor® Flea and Tick Collar for Medium Dogs
{ABN} PetArmor® Flea and Tick Collar for Large Dogs
{ABN} [SENTRY Flea & Tick Collar for Small Dogs & Puppies]
{ABN} [SENTRY Flea & Tick Collar for Large Dogs]
{ABN} [SENTRY Flea & Tick Collar for Dogs & Puppies]
{ABN} [Sentry Vet Flea & Tick Collar for Dogs]
{ABN} [Sergeant's Dual Action Flea & Tick Collar II for Small Dogs & Puppies]
{ABN} [Sergeant's Dual Action Flea & Tick Collar II for Dogs]
{ABN} [Sergeant's Dual Action Flea & Tick Collar II for Large Dogs]

ACCEPTED

04/03/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended for this
pesticide registered under
EPA Reg. No. 2517-166

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 2 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

[Compare to Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs], contains [the] same active ingredient.*]

[Compare to Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs], contains [the] same active ingredient deltamethrin.*]

[Compare to the [an] [same] active ingredient found in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs]*]

[[Brand Name] [This product] contains deltamethrin, [the] [an] [same] active ingredient used in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs].*]

*Scalibor® is a registered trademark of [Merck Animal Health] [Intervet International]. [Brand Name] is not manufactured by distributed by Merck Animal Health.

Fleas

- [Kills Fleas [for up to 6 months]]
- [Kills fleas that may cause anemia]
- [Kills fleas that may cause bartonellosis]
- [Kills fleas that may transmit tapeworms.]
- [Kills [adult] fleas that may cause [Flea Allergy Dermatitis (FAD)][and][flea bite dermatitis]]
- [Kills fleas and may reduce the incidence of FAD]
- [Kills fleas that may cause anaplasmosis]
- [Kills [adult] fleas which may cause flea bite anemia]
- [Kills [adult] fleas which may transmit tapeworms]
- [Kills Fleas for up to [3] [three] [months] [90 days] [4] [four] [months] [120 days] [5] [five] [months] [150 days] [6] [six] [months] [180 days] [!]]]
- [Kills fleas which may be a source of flea allergy dermatitis][(and) flea bite anemia][(and)tapeworm]
- [Prevents new flea infestations]
- [Kills adult fleas (before they lay eggs)]
- [Flea (control) (prevention) for dogs (& puppies)]

Ticks

- [Kills Ticks[for up to 6 months]]
- [Kills ticks for up to [3][three][months][90 days][4][four][months][120 days][5][five][months] [150 days][6][six][months] [180 days][!]]]
- [Kills the Ticks that may carry Rocky Mountain Spotted Fever]
- [Kills ticks that may cause babesiosis]
- [Kills ticks for 6 months, including Deer ticks (vector of Lyme disease and anaplasmosis), American dog ticks (vector of Rocky Mountain spotted fever and ehrlichiosis), and Brown dog ticks (vector of ehrlichiosis, anaplasmosis, bartonellosis, canine hemoplasmosis, babesiosis)]
- [Kills ticks that may transmit disease]
- [Tick (control)(prevention) for dogs (& puppies)]
- [Kills ticks (including deer ticks which may carry Lyme disease)]
- [Provides [long lasting][6 month] protection against ticks]

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 3 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

Multiple Pests

- [Kills Fleas and Ticks [for up to 6 Months]]
- [Provides [up to] [6] [six] [months] control [of fleas [and] [&] ticks]
- [Kills Fleas [and] [&] Ticks]

Collar Fit Claims

- [Lock and Stay Design]
- [Click and Stay Design]
- [Click to Fit Design]
- [Fits Just Right [Design]]
- [Comfort Fit [Design]]
- [Designed for Comfort]
- [Rugged][and][weatherproof]
- [Time Release formula]
- [Modern Click to Fit Design]
- [Pull and Click]
- [Best Fitting Flea Collar]
- [Stay in Place design]
- [Clicks into place]
- [Won't slide and stretch]
- [Won't be too loose or too tight]
- [Won't be too loose or too tight [...fits just right [!]]]
- [Fits just right [Design]]
- [Fits just right ... won't be too loose or too tight]
- [Right Size Collar [Design]]
- [[New] Lock and Fit Design]
- [Slide [to] [and] Fit [Design]]
- [Fits securely] [Stays in place]
- [Fit] [-] [and] Stay {Design}]
- [Slide Fit [and] Stay Design]
- [Right Fit [Design]]
- [Right fit [Design]]
- [Just Right Fit [Design]]
- [Fits neck up to [26"]
- [Fits Neck to [specific inch size]]
- [Notched to fit securely on any size dog]
- [Fits securely on any size dog]
- [Grrreat Fit]
- [GRR...eat FIT]
- [Grr.eat [Fit]]
- [Adjustable]
- [Fits all size dogs]

All Other

- [Long Lasting Protection [for up to 6 months]]
- [Provides up to 6 months control [of fleas and ticks]]
- [Continuous protection]
- [For [Dogs], [Large Dogs], [Medium Dogs] [Small Dogs & Puppies] [Small Breeds]]
- [Deodorizes]
- [Deodorizing]

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 4 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

- [[Fresh][Powdery][Clean] Scent]
- [Specific fragrance noted here][Scent][Fragrance]]
- [Fits Neck to [15"] [20"] [23"]]
- [Fits Neck to [specific inch size]]
- [[Features] insecticide-release technology]
- [Wetting will not impair the collar's effectiveness or the pet's protection]
- [Not affected by water] [Water resistant] [Waterproof]
- [All Weather Collar]
- [Sergeant's collar technology]
- [Convenient]
- [Easy to (use)(apply)(attach)]
- [Apply new collar every 6 months]
- [For dog (and puppies) 12 weeks of age and older]
- [Specific printed design described here (i.e., animal paw print, paw print, etc.)][print][design][collar]
- [*over [12] weeks of age]
- [For dog(s) (and puppies) 12 weeks of age and older]
- [Reflective][Stylish][Trendy][Fashion][Glow-in-the Dark][Collar Cover][Protector Band][Collar Embellishment][Collar Accessories]
- [Designed] [and] [Tested] to work [exclusively][specifically] with [Brand Name]
- [Pup-cessory]
- [Fits right over existing collar]
- [Value Pack]
- [Multi][][Pack]
- [Buy More and Save]
- [Buy [X] Get [X] Free]
- [Buy [X] and Save]
- [Bonus Pack]
- [For multiple dog [and puppy] households]

ACTIVE INGREDIENT:

Deltamethrin4.0%

OTHER INGREDIENTS 96.0%

Total 100.0%

DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR

CAUTION

See [Back] [Insert] [or] [Side] Label [Panel(s)] for Additional Precautionary Statements

Net Weight: [[Small] 0.65oz. (18.4g)] [[Medium] 0.85oz. (24.1g)] [[Large] 0.97oz. (27.5g)]
[Multi Packs] [[XX oz](XX g)]

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 5 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

{Product Name}

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON [DOGS] [MEDIUM DOGS] [SMALL DOGS]
[SMALL BREEDS] [PUPPIES]
[DO NOT USE ON CATS]

[PRODUCT INFORMATION]

[[{Product Name} [This collar kills fleas and ticks for up to 6 months.] Collar is a [double layer] sustained-release system [containing deltamethrin] combining the insecticidal actions of vapors and powders [working in [two] [three] ways to provide head to tail protection]. Thus, collar has the effect of simultaneous usage of a spray and powder [in the control of fleas and ticks, including ticks that may carry Rocky Mountain spotted fever]. Use {Product Name} year round for most effective control. [Replace every 6 months or sooner if needed.]]

[[{Product Name}], containing deltamethrin insecticide, has been specially formulated using [patented] insecticide-release technology. [Maximum effectiveness may not occur for 2-3 weeks after collar placement.] [If your dog is infested, you may consider shampooing your dog with an EPA registered [brand name] [flea and tick shampoo] to provide immediate relief from itching and biting before applying the [collar][product name]. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalu sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*), which may carry the Lyme disease. This collar should be worn continuously.]
[Reapply a new collar every 6 months.]

PRECAUTIONARY STATEMENTS **HAZARDS TO HUMANS AND DOMESTIC ANIMALS** **CAUTION**

Do not open protective [pouch][package] until ready to use. Do not let children play with this collar. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Do not use on cats. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide and is not to be taken internally by humans or animals.

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 6 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

| FIRST AID | |
|--|---|
| IF SWALLOWED: | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| IF ON SKIN OR CLOTHING: | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |
| IF IN EYES: | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-781-4738 for emergency medical treatment information. | |

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not open until ready to use. Dust [will][may] form on collar during storage. Do not get dust in mouth or eyes.] Place collar around pet's neck, adjust for fit, and buckle in place. The collar must be worn loosely to allow for growth of the pet and to permit the collar to move about the neck. Generally, a properly fitted collar is one that when fastened, will snugly slide over pet's head. Leave 2 or 3 inches for extra adjustment. Cut off and dispose of excess length. Wash hands after [installing] [placing] collar on pet. Replace collar every six months or sooner if needed.

[OPTIONAL ALTERNATE DIRECTIONS FOR USE FOR INJECTION MOLDED COLLARS]

[[1.] Do not open until ready to use. Dust [will] form on collar during storage. Do not get dust in mouth or eyes. Take the collar out of the packaging and stretch to full length. [The tabs that held the collar in place [should]][will] fall off when stretching; pull on any remaining tabs to remove them.]

Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 7 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

[[2.] Bend the buckle in half between the holes in the buckle, so that you can easily pass the end of the collar through both holes.]

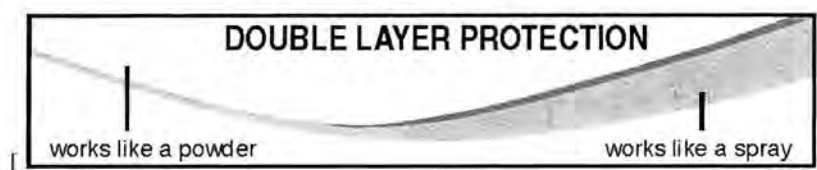


[[3.] Place the collar around your pet's neck. Feed the collar through both holes [[ridges][notches] facing out]. Fit to the neck of the dog. The collar must be worn loosely to allow for growth of the pet and to permit the collar to move about the neck. Generally, a properly fitted collar is one that, when fastened, will snugly slide over pet's head[, and two fingers can be placed between the collar and pet's neck]. Leave [2 or 3] [1 or 2] extra inches for collar adjustment, cut off remaining excess collar and dispose of in the trash.]



[4.] Wash hands after[installing] [placing] collar on pet. Replace collar every 6 months, or sooner if needed.]

[(INSERT DIAGRAM THAT DEPICTS DOUBLE LAYER PROTECTION OF PRODUCT)]



Sergeant's Master Label

22 January 2015 Fast Track Amendment
Information in [] is optional.

Version 15.1
Page 8 of 8

EPA Reg. No. 2517-166
EPA SAL 3 June 2014

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **Pesticide Storage:** Store this product in a cool, dry place away from children and pets. **Pesticide and Container Disposal:** Do not reuse container or used collar. Dispose of in trash.

[WARRANTY]

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to be adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[Satisfaction guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

[If you have questions or comments about this product, please write:

[SENTRY][Sergeant's] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call 1-800-224-PETS (7387)

[Product Coupons on inside or outside of package]
[Made in USA] {lot, date & label code}

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399

[BAR CODE AREA]
EPA Reg. No. 2517-XXX
EPA Est. No. XXXXX-XX-XXX

{END - BACK / SIDE PANEL}

Rudick, Maggie

From: Prince Bamaze <Prince.Bamaze@perrigo.com>
Sent: Tuesday, March 03, 2015 5:40 PM
To: Rudick, Maggie
Cc: Kelly Hoskins
Subject: RE: Label Requested - EPA Reg # 2517-166
Attachments: 2517-166 with EPA requested correction.pdf

Maggie,

Please see attached, with EPA requested corrections.

Regards,

Prince Bamaze | Regulatory Affairs Associate
Perrigo Animal Health

T: (402) 938-7065

F: (402) 938-7165

E: prince.bamaze@perrigo.com | perrigoanimalhealth.com

From: Rudick, Maggie [mailto:Rudick.Maggie@epa.gov]
Sent: Tuesday, March 03, 2015 4:19 PM
To: Prince Bamaze
Cc: Kelly Hoskins
Subject: RE: Label Requested - EPA Reg # 2517-166

Prince –

We are okay with the revisions made provided you remove the [brackets] around the first 2 comparative claims highlighted in the attachment provided.

Please send a revised email back to me with these brackets removed.

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
(703) 347-0257
Rudick.Maggie@epa.gov

From: Prince Bamaze [mailto:Prince.Bamaze@perrigo.com]
Sent: Thursday, February 26, 2015 9:01 AM
To: Rudick, Maggie
Cc: Kelly Hoskins; Prince Bamaze
Subject: RE: Label Requested - EPA Reg # 2517-166

Good Morning Maggie,

I am just following up on this to make sure you have received the pdf copy of EPA Reg. No. 2517-166 labeling submitted back on January 22nd.

Please let me know if anything else is needed to move the process along.

Have a great Day.

Hello Maggie,

Attached is a PDF version of the label Amendment for product Reg. No. 2517-166 submitted January 22, 2015.

Please let me know if you need anything else.

Best Regards,

Prince Bamaze | Regulatory Affairs Associate
Perrigo Animal Health

T: (402) 938-7065

F: (402) 938-7165

E: prince.bamaze@perrigo.com | perrigoanimalhealth.com

From: Rudick, Maggie [<mailto:Rudick.Maggie@epa.gov>]

Sent: Monday, February 23, 2015 12:50 PM

To: Prince Bamaze

Cc: Prince Bamaze

Subject: RE: Label Requested - EPA Reg # 2517-166

Prince –

Can you please email me an electronic version of your proposed labeling sent in 1/22/15 for fast track review.

Thank you,

Maggie Rudick

U. S. Environmental Protection Agency

Office of Pesticides Program

Registration Division; Invertebrate & Vertebrate Branch I

(703) 347-0257

Rudick.Maggie@epa.gov

From: Rudick, Maggie

Sent: Wednesday, January 21, 2015 9:27 AM

To: 'Prince Bamaze'



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 2, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

PRODUCT NAME: SPCP4
COMPANY NAME: SERGEANT'S PET CARE PRODUCTS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2517-166
EPA RECEIPT DATE: 01/30/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 306-0415.

Sincerely,

A handwritten signature in black ink, appearing to be "S".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

January 22, 2015

Kable Bo Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (AMND)
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Subject: Application for Pesticide Amendment
For Deltamethrin Collar SPCP4, EPA Registration No. 2517-166

Dear Mr. Davis,

In response to the Agency letter dated January 21, 2015 regarding a previous label amendment submitted on September 25, 2014, Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting a new label amendment to revise master label for the end-use product, SPCP4, to add new marketing claim and Alternate Brand Names. The added claim refers to a comparable product (EPA Reg. No. 68451-1) containing same active ingredient, deltamethrin. The new claim is as following:

[Compare to Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs], contains [the] [same] active ingredient.*]

[Compare to Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs], contains [the] [an] [same] active ingredient deltamethrin.*]

[Compare to the [an] [same] active ingredient found in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs]*]

[[Brand Name] [This product] contains deltamethrin, [the] [an] [same] active ingredient used in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs].*]

*Scalibor® is a registered trademark of [Merck Animal Health] [Intervet International]. [Brand Name] is not manufactured by distributed by Merck Animal Health.

Additionally, and as provided by PR Notice 98-10, Sergeant's is requesting Agency approval of the following new Alternate Brand Names for EPA Reg. No. 2517-166:

[PetArmor® Collar for Dogs]
[PetArmor® Collar for Small Dogs]
[PetArmor® Collar for Small Dogs and Puppies]
[PetArmor® Collar for Dogs and Puppies]
[PetArmor® Collar for Medium Dogs]
[PetArmor® Collar for Large Dogs]
[PetArmor® Flea and Tick Collar for Dogs]
[PetArmor® Flea and Tick Collar for Small Dogs]

Mr. Kable Bo Davis
January 22, 2015
Page 2

[PetArmor® Flea and Tick Collar for Small Dogs and Puppies]
[PetArmor® Flea and Tick Collar for Dogs and Puppies]
[PetArmor® Flea and Tick Collar for Medium Dogs]
[PetArmor® Flea and Tick Collar for Large Dogs]
[SENTRY Flea & Tick Collar for Small Dogs & Puppies]
[SENTRY Flea & Tick Collar for Large Dogs]
[SENTRY Flea & Tick Collar for Dogs & Puppies]
[Sentry Vet Flea & Tick Collar for Dogs]
[Sergeant's Dual Action Flea & Tick Collar II for Small Dogs & Puppies]
[Sergeant's Dual Action Flea & Tick Collar II for Dogs]
[Sergeant's Dual Action Flea & Tick Collar II for Large Dogs]

In support of this submission please find enclosed:

1. Application for Pesticide Registration, EPA Form 8570-1
2. Two copies of revised master label (with highlights)
3. One copy of revised master label (clean)

No other changes or revisions are being made to the most recent EPA accepted label dated June 3, 2014 at this time.

Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at pbamaze@sergeant's.com

Sincerely,



Prince M. Bamaze
Regulatory Associate

Enclosures

| | | | |
|--|---|---|---|
| EPA United States Environmental Protection Agency Washington, DC 20460 | | <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other | OPP Identifier Number |
| Application for Pesticide - Section I | | | |
| 1. Company/Product Number 2517-166 | | 2. EPA Product Manager Richard Gebken | |
| 4. Company/Product (Name) Sergeant's Pet Care Products, Inc./ SPCP 4 | | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted | |
| 5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: | |
| | | EPA Reg. No. _____ Product Name _____ | |
| Section II | | | |
| <input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below. | | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below. | |
| Explanation: Use additional page(s) if necessary. (For section I and Section II.) Label Amendment to add new marketing claim/language (Non-PRIA action), and Alternate Brand Names. Please see cover letter for details. | | | |
| Section III | | | |
| 1. Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container <div style="text-align: center;"> </div> | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Package wgt. Container <div style="text-align: center;"> </div> | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container fl oz | |
| | | 5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | |
| Section IV | | | |
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name Prince M. Bamaze | | Title Regulatory Associate | |
| | | Telephone No. (include Area Code) 402-938-7065 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received (Stamped) <div style="text-align: center; font-size: 1.2em;">18</div> |
| 2. Signature BY: Prince M. Bamaze | | 3. Title Regulatory Affairs | |
| 4. Typed Name: Prince M. Bamaze | | 5. Date: 22 January, 2015 | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 21, 2015

Prince M. Bamaze
Sergeant's Pet Care Products, Inc.
10077 South 134th St.
Omaha, NE 68138

Subject: Unacceptable Label Amendment – Add Alternate Brand Names and Marketing Claims
Product Name: SPCP4
EPA Registration Number: 2517-166
Application Date: September 25, 2014
Decision Number: 496680

Dear Mr. Bamaze:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is not acceptable for the following reason:

1. The proposed marketing claim, "*Compare to Scalibor® [Protector band][Tick and Flea][collar][for dogs] [same] active ingredient**" is not acceptable. It could be confused for a direct comparison.

Therefore, your application is not acceptable. No further processing of this application will occur. If you have any questions, please contact Maggie Rudick at 703-347-0257 or by email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis".

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Rudick, Maggie

From: Davis, Kable
Sent: Wednesday, January 21, 2015 9:21 AM
To: Rudick, Maggie
Subject: RE: Label Requested - EPA Reg # 2517-166
Attachments: 2517-166 Unacceptable Letter.pdf

Here you go.

From: Rudick, Maggie
Sent: Wednesday, January 21, 2015 9:18 AM
To: Davis, Kable
Subject: FW: Label Requested - EPA Reg # 2517-166

Bo –

Here is the Agency letter turning down this company's amendment.

Maggie

From: Prince Bamaze [<mailto:Prince.Bamaze@perrigo.com>]
Sent: Wednesday, January 14, 2015 1:25 PM
To: Rudick, Maggie
Cc: Kelly Hoskins; Davis, Kable
Subject: RE: Label Requested - EPA Reg # 2517-166

Hello Maggie,

Please note that the marketing claim as stated has been approved by the Agency for numerous products including for Sergeant's EPA Reg. No. 2517-134. Given those approvals, Sergeant's would like to keep the claim on the 2517-166 as is for marketing consistency. For marketing options, Sergeant's will use the statement you suggested in your e-mail of January 8th, 2015 in addition to our initial statement, again consistent with the 2517-134 approved label. For your convenience I attached a copy of Sergeant's EPA Reg. No. 2517-134 and a clean revised version of EPA Reg. No. 2517-166 for your approval.

Please let me know if anything else is needed.

Best Regards,

Prince Bamaze | Regulatory Affairs Associate
Perrigo Animal Health
T: (402) 938-7065
F: (402) 938-7165
E: Prince.Bamaze@perrigo.com | perrigoanimalhealth.com

From: Rudick, Maggie [<mailto:Rudick.Maggie@epa.gov>]
Sent: Thursday, January 08, 2015 11:36 AM
To: Prince Bamaze
Subject: RE: Label Requested - EPA Reg # 2517-166

Prince –

The marketing statement revision is even more confusing than the original one. Marketing claims cannot be direct comparisons to products, but only comparing the active ingredient. Also, you cannot put (or any ABN).

You can revise the claim to read:

“Compare to same active ingredient found in Scalibor [Protector band][Tick and Flea] [collar][for dogs] .”

Otherwise, please just remove this claim from your label.

Please let me know if you have any further questions.

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
(703) 347-0257
Rudick.Maggie@epa.gov

From: Prince Bamaze [<mailto:Prince.Bamaze@perrigo.com>]
Sent: Monday, January 05, 2015 4:37 PM
To: Rudick, Maggie
Cc: Prince Bamaze
Subject: RE: Label Requested - EPA Reg # 2517-166

Hi Maggie,

Please find attached a revised label with all additional corrections you requested.

Please let me know if you need anything else.

Have a great afternoon!

Prince Bamaze | Regulatory Affairs Associate
Perrigo Animal Health
T: (402) 938-7065
F: (402) 938-7165
E: Prince.Bamaze@perrigo.com | perrigoanimalhealth.com

From: Rudick, Maggie [<mailto:Rudick.Maggie@epa.gov>]
Sent: Monday, January 05, 2015 2:57 PM
To: Prince Bamaze
Cc: Prince Bamaze
Subject: RE: Label Requested - EPA Reg # 2517-166

From: Rudick, Maggie
Sent: Monday, January 05, 2015 10:04 AM

To: 'Prince Bamaze'

Subject: RE: Label Requested - EPA Reg # 2517-166

Prince –

Per our secondary review, we are requesting a few minor revisions. Please let me know if you have any further questions. A clean copy of your label can be emailed to me.

Maggie Rudick

U. S. Environmental Protection Agency

Office of Pesticides Program

Registration Division; Invertebrate & Vertebrate Branch I

(703) 347-0257

Rudick.Maggie@epa.gov

From: Prince Bamaze [<mailto:Prince.Bamaze@perrigo.com>]

Sent: Tuesday, December 30, 2014 10:28 AM

To: Rudick, Maggie

Cc: Prince Bamaze

Subject: RE: Label Requested - EPA Reg # 2517-166

Hi Maggie,

You are correct that the intension is to deactivate the crossed out ABNs, as shown on the attached "clean" label. Also, inert ingredients is replaced with other ingredients as you requested. The brackets are removed on the revised, attached label to make DFU non optional.

Please let me know if you need anything else for approval of this label.

Have a fantastic year 2015!

Prince Bamaze | Regulatory Affairs Associate

Perrigo Animal Health

T: (402) 938-7065

F: (402) 938-7165

E: Prince.Bamaze@perrigo.com | perrigoanimalhealth.com

From: Rudick, Maggie [<mailto:Rudick.Maggie@epa.gov>]

Sent: Monday, December 29, 2014 1:46 PM

To: Prince Bamaze

Subject: RE: Label Requested - EPA Reg # 2517-166

Prince –

Thanks for sending this over. On your highlighted version of the label, you have some ABNs crossed out – is it your intention to make these inactive?

One minor label change to be made – change *inert* ingredients to *other* ingredients.

Lastly, can you please clarify the intentions of the DFU? Everything is bracketed, which you say is optional language. Can you somehow clarify that you will include either [A DFU] or [B DFU] or something of that sort.

Please send a revised label back to me for approval.

Thank you and happy new year!

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
(703) 347-0257
Rudick.Maggie@epa.gov

From: Prince Bamaze [<mailto:PBamaze@SERGEANTS.COM>]
Sent: Tuesday, December 23, 2014 11:49 AM
To: Rudick, Maggie
Cc: prince.bamaze@perrigo.com
Subject: RE: Label Requested - EPA Reg # 2517-166

Hello Maggie,

Please find attached both pdf and Word copies for EPA registered label No. 2517-166.

Also, the EPA Registration No. for the "Me-too" product Scalibor is **68451-1**.

Please let me know if anything else is needed, and have a great holiday season as well!

Best regards,

Prince Bamaze | Regulatory Affairs Associate
Perrigo Animal Health
T: (402) 938-7065
F: (402) 938-7165
E: Prince.Bamaze@perrigo.com | perrigoanimalhealth.com

From: Rudick, Maggie [<mailto:Rudick.Maggie@epa.gov>]
Sent: Tuesday, December 23, 2014 9:49 AM
To: Prince Bamaze; pbamaze@sergeant.com
Subject: RE: Label Requested - EPA Reg # 2517-166

Prince –

One additional question – can you please provide the EPA Registration number for your "comparative" product – Scalibor?

Maggie Rudick
Registration Division
Invertebrate & Vertebrate Branch I
703-347-0257

From: Rudick, Maggie
Sent: Tuesday, December 23, 2014 10:41 AM
To: 'pbamaze@sergeants.com'; 'pbamaze@sergeant.com'
Subject: Label Requested - EPA Reg # 2517-166

Prince —

Can you please email me a PDF text searchable version of your proposed labeling for EPA Reg # 2517-166. You had submitted a label amendment on 9/25/14 for review and we need an electronic version of the label to move forward.

Thank you and enjoy your holidays!

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
(703) 347-0257
Rudick.Maggie@epa.gov

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please immediately notify us by return e-mail and delete this message and any attachments from your computer system. Please note that if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please immediately notify us by return e-mail and delete this message and any attachments from your computer system. Please note that if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please immediately notify us by return e-mail and delete this message and any attachments from your computer system. Please note that if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 14, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

PRODUCT NAME: SPCP4
COMPANY NAME: SERGEANT'S PET CARE PRODUCTS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2517-166
EPA RECEIPT DATE: 10/10/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 13, at (703) 305-0120.

Sincerely,

A handwritten signature in black ink, appearing to be "SG" or similar, written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Septembre 25, 2014

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (AMND)
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Re: Application for Pesticide Amendment (Non-PRIA)
for SPCP4, EPA Registration No. 2517-166

Dear Mr. Gebken:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting an application for pesticide amendment to revise the master label for the end-use product, SPCP4, to add new marketing claims and Alternate Brand Names. The added claims are related to a comparative product containing same active ingredient. The new claim is as following:

Compare to Scalibor® [Protector band][Tick and Flea][collar][for dogs][same] active ingredient*
Contains deltamethrin, the [same] active ingredient used in Scalibor® [Protector band][Tick and Flea][collar][for dogs]*

*Scalibor® is a registered trademark of [Merck Animal Health] [Intervet International]. [Brand Name] is not manufactured by distributed by Merck Animal Health.

Additionally, and as provided by PR Notice 98-10, Sergeant's is requesting Agency approval of the following new Alternate Brand Names for the 2517-166:

[PetArmor® Collar for Dogs]
[PetArmor® Collar for Small Dogs]
[PetArmor® Collar for Small Dogs and Puppies]
[PetArmor® Collar for Dogs and Puppies]
[PetArmor® Collar for Medium Dogs]
[PetArmor® Collar for Large Dogs]

[PetArmor® Flea and Tick Collar for Dogs]
[PetArmor® Flea and Tick Collar for Small Dogs]
[PetArmor® Flea and Tick Collar for Small Dogs and Puppies]
[PetArmor® Flea and Tick Collar for Dogs and Puppies]
[PetArmor® Flea and Tick Collar for Medium Dogs]
[PetArmor® Flea and Tick Collar for Large Dogs]
[SENTRY Flea & Tick Collar for Small Dogs & Puppies]
[SENTRY Flea & Tick Collar for Large Dogs]

Mr. Richard Gebken
September 25, 2014
Page 2

[SENTRY Flea & Tick Collar for Dogs & Puppies]
[Sentry Vet Flea & Tick Collar for Dogs]
[Sergeant's Dual Action Flea & Tick Collar II for Small Dogs & Puppies]
[Sergeant's Dual Action Flea & Tick Collar II for Dogs]
[Sergeant's Dual Action Flea & Tick Collar II for Large Dogs]

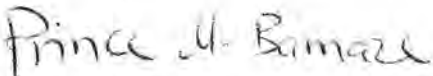
In support of this submission please find enclosed:

1. Application for Pesticide Registration, EPA Form 8570-1
2. Two copies of revised master label (with highlights)
3. One copy of revised master label (clean)

No other changes or revisions are being made to the most recent EPA accepted label dated June 3, 2014 at this time.

Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at pbamaze@sergeant's.com

Sincerely,



Prince M. Bamaze
Regulatory Associate

Enclosures

| | | |
|---|---|-----------------------|
| <h1 style="margin: 0;">EPA</h1> <p style="text-align: center; margin: 0;">United States Environmental Protection Agency Washington, DC 20460</p> | <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other | OPP Identifier Number |
|---|---|-----------------------|

Application for Pesticide - Section I

| | | |
|--|--|--|
| 1. Company/Product Number 2517-166 | 2. EPA Product Manager Richard Gebken | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Sergeant's Pet Care Products, Inc./ SPCP 4 | 5. PM# 10 | |
| 5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

Section II

| | |
|--|--|
| <input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below. |
|--|--|

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment to add new marketing claim/language (Non-PRIA action), and Alternate Brand Names. Please see cover letter for details.

Section III

| | | | | | |
|---|--|---|---|--|-------------------------|
| 1. Material This Product Will Be Packaged In: | | | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag | | |
| *Certification must be submitted | | If "Yes" Unit Packaging wgt. _____ | No. per Container _____ | If "Yes" Package wgt. _____ | No. per Container _____ |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container fl oz _____ | | 5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | | |

Section IV

| | | |
|--|----------------------------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Prince M. Bamaze | Title Regulatory Associate | Telephone No. (Include Area Code) 402-938-7065 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature BY: Prince M. Bamaze | 3. Title Regulatory Associate | |
| 4. Typed Name: Prince M. Bamaze | 5. Date: 25 September, 2014 | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 10 2014

Mr. Prince M. Bamaze
Regulatory Associate
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Label Notification per PRN 98-10 – Addition of a new Alternate Brand Names and Marketing Claims to the Sergeant's Master Label
Product Name: **SPCP 4**
EPA Registration Number: 2517-166
Application Date: August 25, 2014
Decision Number: 494988

Dear Mr. Bamaze:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the request is not acceptable for the following reasons:

1. The comparative claim referenced on your label "Compare to Scalibor® [Protector band][Tick and Flea] [collar][for dogs][same] active ingredient* Contains deltamethrin, the [same] active ingredient used in Scalibor® [Protector band][Tick and Flea][collar][for dogs]* Please refer to the comparative claim guidance document available on the Agency's web site at: <http://www.epa.gov/pesticides/regulating/labels/pdf/metoo.pdf>. These types of claims must be submitted as an amendment, and do not clearly fall within PR Notice 98-10.

No further processing of this application will occur. You may submit a new application addressing the deficiencies listed above for future consideration. Our records have been updated accordingly to note that this notifications is unacceptable.

Page 2 of 2
EPA Reg. No. 2517-166
Decision No. 494988

If you have any questions, you may call Dani Daniel at 703 305-5409 or via email at daniel.dani@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken", with a stylized flourish at the end.

Richard J. Gebken, Product Manager 10
Insecticide Branch
Registration Division (7505P)
Office of Pesticide Programs

August 25, 2014

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Re: Submission of Label Notification per PR Notice 98-10 for SPCP 4,
EPA Registration No. 2517-166

Dear Mr. Gebken:

Please consider this Notification of additional new Alternate Brand Names and marketing claims to Sergeant's Pet Care Products, Inc. Master Label for SPCP 4, EPA Registration Number 2517-166. The added claims are related to a comparative product containing same active ingredient. In support of this Notification please find enclosed the following:

1. Application for Pesticide Registration, EPA Form 8570-1
2. Two copies of revised master label (with highlights)
3. One copy of revised master label (clean)

As provided by PR Notice 98-10, Sergeant's is requesting Agency approval of the following new Alternate Brand Names for the 2517-166:

[PetArmor® Collar for Dogs]
[PetArmor® Collar for Small Dogs]
[PetArmor® Collar for Small Dogs and Puppies]
[PetArmor® Collar for Dogs and Puppies]
[PetArmor® Collar for Medium Dogs]
[PetArmor® Collar for Large Dogs]

[PetArmor® Flea and Tick Collar for Dogs]
[PetArmor® Flea and Tick Collar for Small Dogs]
[PetArmor® Flea and Tick Collar for Small Dogs and Puppies]
[PetArmor® Flea and Tick Collar for Dogs and Puppies]
[PetArmor® Flea and Tick Collar for Medium Dogs]
[PetArmor® Flea and Tick Collar for Large Dogs]
[SENTRY Flea & Tick Collar for Small Dogs & Puppies]
[SENTRY Flea & Tick Collar for Large Dogs]
[SENTRY Flea & Tick Collar for Dogs & Puppies]
[Sentry Vet Flea & Tick Collar for Dogs]
[Sergeant's Dual Action Flea & Tick Collar II for Small Dogs & Puppies]
[Sergeant's Dual Action Flea & Tick Collar II for Dogs]
[Sergeant's Dual Action Flea & Tick Collar II for Large Dogs]

Mr. Richard Gebken
August 25, 2014
Page 2

Additionally, Sergeant's is requesting Agency approval of the following marketing claims:

Compare to Scalibor® [Protector band][Tick and Flea][collar][for dogs][same] active ingredient*
Contains deltamethrin, the [same] active ingredient used in Scalibor® [Protector band][Tick and Flea][collar][for dogs]*

*Scalibor® is a registered trademark of [Merck Animal Health][Intervet International]. [Brand Name] is not manufactured by distributed by Merck Animal Health.

No other changes or revisions are being made to the most recent EPA accepted label dated June 3, 2014 at this time.

Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at pbamaze@sergeant's.com

Sincerely,



Prince M. Bamaze
Regulatory Associate

Enclosures

EPA

United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other**

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|--|
| 1. Company/Product Number 2517-166 | 2. EPA Product Manager Richard Gebken | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Sergeant's Pet Care Products, Inc./ SPCP 4 | 5. PM# 10 | |
| 5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

Section II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated |
| <input type="checkbox"/> Resubmission in response to Agency letter dated | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification adds Alternate Brand Names to the label for this product: SPCP 4. This Notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10, and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

| | | | | | |
|---|--|---|--|--|--|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | | | |
| *Certification must be submitted | | | | | |
| If "Yes" Unit Packaging wgt. | | No. per Container | | | |
| | | | | | |
| If "Yes" Package wgt. | | No. per Container | | | |
| | | | | | |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container fl oz | | 5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | | |

Section IV

| | | |
|--|----------------------------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Prince M. Bamaze | Title Regulatory Associate | Telephone No. (Include Area Code) 102-028-7065 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 8. Date Application Received (Stamped) |
| 2. Signature BY: Prince M. Bamaze | 3. Title Regulatory Associate | |
| 4. Typed Name: Prince M. Bamaze | 5. Date: 25 August, 2014 | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 419131; **FILE SYMBOL No.:** 2517-RAA(a); **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

DATE OUT: April 21, 2014

SUBJECT: End Use Product Chemistry Review
Product Name: SPCP4

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S. Mathur
4-22-14
JCR

TO: Linda DeLuise / Richard Gebken, RM 10
Herbicide Branch / RD (7505P)

Company Name: Seargent's Pet Care Products Incorporation
Formulation Type: Insecticide

INTRODUCTION:

The product chemistry data for the new end use product SPCP4 submitted under MRID Nos. 492107-01 and 492107-02 and proposed basic and alternate CSF's (all dated 09-12-2013) were reviewed previously by TRB (see PCR dated 02-10-2014, DP415944). It was concluded that the all the product chemistry data submitted were found to be acceptable, except for the proposed basic & alternate CSF's due the presence of non-approved inert ingredients. The registrant has re-submitted the revised basic & alternate CSF's #1 to #3 (all dated March 26, 2014) containing the inert ingredients which have now been approved by the Agency. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 68451-1. TRB has been asked to determine the acceptability of the proposed basic & alternate CSF's and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Deltamethrin (4.0%)
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes, give the registration number of the cited product.

Reg. No. 68451-1

3. All of the source materials of the active ingredient are derived from registered sources: ☒ Yes ☐ No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: ☒ Yes; ☐ No

5. Confidential Statement of Formula(s):

☒ Proposed Basic - Dated: 09-12-2013; Resubmitted – Dated: 03-26-2014

☒ Proposed Alternate CSF's #1 to #3 – All Dated: 09-12-2013; Resubmitted – Dated: 03-26-2014

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA;

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

7. Group A: Product Chemistry Data

| Guideline No. | Study Title | | Data submitted | | TRB's Assessment of Data | MRID Nos. Cited |
|---------------|--|--------------------------------|----------------|----|--------------------------|------------------------------|
| | | | Yes | No | | |
| 830.1550 | Product Identity & Composition | | X | | A | 492107-01 |
| 830.1600 | Description of materials used to produce the product | | X | | A | 492107-01 |
| 830.1650 | Description of formulation process | | X | | A | 492107-01 |
| 830.1670 | Discussion on the formation of impurities | | X | | A | 492107-01 |
| 830.1700 | Preliminary analysis | | | | | |
| 830.1750 | Certified limits (158.350) | Standard certified limits | X | | | Revised Basic CSF (03-26-14) |
| | | Proposed Limits | | | | |
| | | Justification for wider limits | | | | |
| 830.1800 | Enforcement analytical method | | X | | A | 492107-03 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

8. Group B:

| Guideline No. | Study Title | Value or Qualitative Description | TRB's Assessment of Data | MRID Nos. |
|---------------|---------------------------|---|--------------------------|-----------|
| 830.6303 | Physical State | Flexible PVC Solid | A | 492107-02 |
| 830.6314 | Oxidation/reduction | None | A | 492107-02 |
| 830.6315 | Flammability | NA | A | 492107-02 |
| 830.6316 | Explosibility | NA | A | 492107-02 |
| 830.6317 | Storage stability | In progress. Will be submitted on completion | I | 492107-02 |
| 830.6320 | Corrosion characteristics | In progress. Will be submitted on completion | I | 492107-02 |
| 830.7000 | pH | NA. Test material is a solid and not dispersible in water | A | 492107-02 |
| 830.7100 | Viscosity | NA | | 492107-02 |
| 830.7300 | Density | 1.2455* g/ml @ 20°C | A | 492107-02 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress

*A one inch piece of collar was cut, measure and placed in a graduated cylinder containing water. Calculation was based on amount of water displaced by collar.

C. CONCLUSIONS:

The TRB has reviewed the proposed basic & alternate CSF's and the supporting product chemistry data for the new end use product and has concluded:

1. The proposed revised CSF for basic formulation & revised CSF's for alternate formulations #1 to #3 (all dated 03-26-2014) are acceptable. All the inert ingredients used in the proposed CSF's are now cleared by the Agency.
2. The product chemistry data submitted corresponding to the guideline 830 series group A are acceptable.
3. The product chemistry data submitted for group B are acceptable. The registrant indicated that the studies for the guideline 830.6317 (1 year storage stability) and 830.6320 (1 year corrosion characteristics) are in progress and the results will be submitted on completion.
4. The proposed product with FSN: 2517-RAA was determined to be substantial similar to the cited product with Reg. No. 68451-1 from the product chemistry point of view.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

2517 PAA
also

sent
4/10/14

DP BARCODE No.: 415947; FILE SYMBOL No.: 2517-RAI; PRODUCT NAME: SPCP3; DECISION No.: 483334; PC Code(s): 097805; ACTION CODE: R310; FOOD Use: No

DATE OUT: April 8, 2014

SUBJECT: End Use Product Chemistry Review
Product Name: SPCP3

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

Bruna
SCR 04/15/14

TO: Linda DeLuise / Deborah McCall, RM 13/ BC
Insecticide Branch / RD (7505P)

Company Name: Sergeant's Pet Care Products Incorporation
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application to register the new end use product SPCP3. The registrant has submitted CSF's for basic formulation and three alternate CSF's #1 to #3 (all dated September 12, 2013). The supporting product chemistry data have been submitted with MRID No. 492107-01 & 492107-02. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 68451-2. TRB has been asked to determine the acceptability of the proposed basic, alternate CSF's and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Deltamethrin (3.0%)
2. Has the registrant claimed substantial similarity to a registered product?
☒ Yes; ☐ No; ☐ NA; if yes, give the registration number of the cited product.
Reg. No. 68451-2

DP BARCODE No.: 415947; FILE SYMBOL No.: 2517-RAI; PRODUCT NAME: SPCP3; DECISION No.: 483334; PC Code(s): 097805; ACTION CODE: R310; FOOD Use: No

3. All of the source materials of the active ingredient are derived from registered sources: ☒ Yes; ☐ No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: ☐ Yes; ☒ No

Note: There are number of the inert ingredients present in the formulations which have not been cleared by the Agency. Additional information is needed with respect to their chemical composition.

5. Confidential Statement of Formula(s):

☒ Proposed Basic - Dated: 09-12-2013; Resubmitted - Dated:

☒ Proposed Alternate CSF #1 to #3 - All Dated: 09-12-2013; Resubmitted - Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?

☒ Yes; ☐ No; if not, explain below:

| | | |
|----------------------|------------------------------|--|
| Metallic equivalent: | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> NA |
| Soluble arsenic: | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> NA |
| Isomeric ratios: | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> NA |
| Acid Equivalent: | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> NA |

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: 415947; FILE SYMBOL No.: 2517-RAI; PRODUCT NAME: SPCP3; DECISION No.: 483334; PC Code(s): 097805; ACTION CODE: R310; FOOD Use: No

7. Group A: Product Chemistry Data

| Guideline No. | Study Title | Data submitted | | TRB's Assessment of Data | MRID Nos. Cited |
|---------------|--|--------------------------------|----|--------------------------|----------------------|
| | | Yes | No | | |
| 830.1550 | Product Identity & Composition | X | | U | 492107-01 |
| 830.1600 | Description of materials used to produce the product | X | | A | 492107-01 |
| 830.1650 | Description of formulation process | X | | A | 492107-01 |
| 830.1670 | Discussion on the formation of impurities | X | | A | 492107-01 |
| 830.1700 | Preliminary analysis | | | | |
| 830.1750 | Certified limits (158.350) | Standard certified limits | X | | Basic CSF (09-12-13) |
| | | Proposed Limits | | | |
| | | Justification for wider limits | | | |
| 830.1800 | Enforcement analytical method | X | | A | 492107-03 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: 415947; FILE SYMBOL No.: 2517-RAI; PRODUCT NAME: SPCP3; DECISION No.: 483334; PC Code(s): 097805; ACTION CODE: R310; FOOD Use: No

8. Group B:

| Guideline No. | Study Title | Value or Qualitative Description | TRB's Assessment of Data | MRID Nos. |
|---------------|---------------------------|---|--------------------------|------------|
| 830.6303 | Physical State | Flexible PVC Solid | A | 492' 07-02 |
| 830.6314 | Oxidation/reduction | None | A | 492' 07-02 |
| 830.6315 | Flammability | NA | A | 492' 07-02 |
| 830.6316 | Explodability | NA | A | 492' 07-02 |
| 830.6317 | Storage stability | In progress. Will be submitted on completion | I | 492' 07-02 |
| 830.6320 | Corrosion characteristics | In progress. Will be submitted on completion | I | 492' 07-02 |
| 830.7000 | pH | NA. Test material is a solid and not dispersible in water | A | 492' 07-02 |
| 830.7100 | Viscosity | NA | | 492' 07-02 |
| 830.7300 | Density | 1.2455* g/ml @ 20°C | A | 492' 07-02 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress

*A one inch piece of collar was cut, measure and placed in a graduated cylinder containing water. Calculation was based on amount of water displaced by collar.

C. CONCLUSIONS:

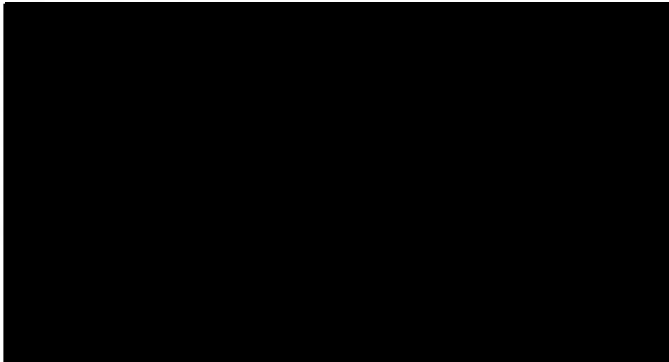
The TRB has reviewed the proposed basic & alternate CSF's and the supporting product chemistry data for the new end use product and has concluded:

1. The proposed CSF's for basic & alternate formulations (all dated 09-12-2013) are not acceptable. The CSF's contain few inert ingredients which are not cleared by the Agency. The registrant must provide additional information on the composition of three inert ingredients. For the names of the inert ingredients please refer to Confidential Appendix.
2. The product chemistry data submitted corresponding to the guideline 830 series group A are partially acceptable. See item #1.
3. The product chemistry data submitted for group B are acceptable. The registrant indicated that the studies for the guideline 830.6317 (1year storage stability) and 830.6320 (1 year corrosion characteristics) are in progress and the results will be submitted on completion.
4. The substantial similarity of the proposed product to the cited product will be determined after the receiving the additional information on the composition on the un-cleared inert ingredient and the approval of the proposed basic and alternate CSF's.

DP BARCODE No.: 415947; FILE SYMBOL No.: 2517-RAI; PRODUCT NAME: SPCP3; DECISION No.: 483334; PC Code(s): 097805; ACTION CODE: R310; FOOD Use: No

CONFIDENTIAL APPENDIX

Additional information on the composition of the following information is required:



INERT CLEARANCE STATUS FORM

| | | | |
|------------------------------|-----|------------------------|------------------|
| Reviewer Name: Tracy Jackson | | Request Date: 10/25/13 | |
| Tel 703-308-7227 | ISB | CUBE: S-4812 | MAIL CODE: 7502P |

A. COMMENTS:

Inerts Issue

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 941278

Date on CSF: 9/

EPA Reg. No/File Symbol: 2517-RAI

Formulation: Ba
Alternate

C. INGREDIENT INFORMATION:

Ingredient No.1

All highlighted items do not have compositional information on file w/ IIRB. Same items identified for 2517 - RAT + - RAA

Comments: Inerts are not found in the EPA database, please provide full compositional information including the manufacturer, constituent names, CAS numbers, and weight percent composition (100% full composition).

Ingredient No. 2

Chem. Name:

Trade Name:

¹Language from the Code of Federal Regulations (40 CFR 180, subpart D):

40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

| | | | | | | | |
|--|--|--|--|--|--|--|--|
| CAS Reg. No.: | | | | | | | |
| Comments: please provide full compositional information including th: manufacturer, constituent names, CAS numbers, and weight percent composition (100% full composition). | | | | | | | |

Reviewer Name: Tracy Jackson

Review Date: 10/25/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

March 7, 2014

MEMORANDUM:

Subject: Name of Pesticide Product: SPCP4 [SERGEANT'S DELTAMETHRIN COLLAR]
EPA Reg. No. /File Symbol: 2517-RAA
DP Barcode: DP 418257
Decision No.: 483206
Action Code: R301
PC Codes: 097805 (Deltamethrin: 4%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
March - 7 - 2014
T.L. Toxicology

To: Linda DeLuise/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

| | |
|------------------------------|---------------|
| <u>Active Ingredient(s):</u> | <u>by wt.</u> |
| 097805 Deltamethrin | 4.00% |
| <u>Other Ingredients:</u> | 96.00% |
| TOTAL | 100.00% |

ACTION REQUESTED: The Risk Manager requests:

"...Do the cited MRIDs in the data matrix support this product?"

BACKGROUND:

The proposed product is a collar for use on dogs and puppies. According to the Application for Pesticide Registration this product is similar or identical in composition and labeling to EPA Reg. No. 68451-1.

COMMENTS AND RECOMMENDATIONS:

1. From the data matrix (dated September 12, 2013) the registrant is citing the following acute toxicity studies: 42889001 (oral toxicity); 42889002 (acute dermal toxicity); 42889003 (primary eye); 42889004 (primary dermal irritation); and 42889005 (dermal sensitization). No inhalation study is cited; this study requirement is normally waived for a pet collar. The registrant is citing 42889006 for the companion animal safety study in dogs.
2. After comparing the CSFs for 68451-1 and 2517-RAA TRB concludes that these two formulations (collars) are toxicologically similar, and that the acute toxicity and companion animal safety studies used to support the registration of 68451-1 will also satisfy these data requirements for 2517-RAA.
3. According to our records, the 5 acute toxicity studies (MRIDs 42889001 through 42889005) were reviewed (Mark Perry, Precautionary Review Section, 5-16-95 for EPA File Symbol 432-TTO; 432-TTO was transferred to 68451-R on March 23, 1995) and classified as acceptable. In addition, the inhalation study data requirement was waived. Based on the PRS review of 5-16-95 the following is the acute toxicity profile of 68451-1 (and, by similarity, 2517-RAA):

| | | |
|-------------------------|----------------|---------------|
| Acute oral LD50 | Tox. Cat. III | MRID 42889001 |
| Acute dermal LD50 | Tox. Cat. III | MRID 42889002 |
| Acute inhalation LC50 | (Tox. Cat. IV) | Waiver |
| Primary eye irritation | Tox. Cat. III | MRID 42889003 |
| Primary skin irritation | Tox. Cat. IV | MRID 42889004 |
| Dermal sensitization | Non-sensitizer | MRID 42889005 |

4. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 2517-RAA, as obtained from the Label Review System:

PRODUCT ID #: 002517-00166

PRODUCT NAME: SPCP4

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The registrant has proposed the statement: "DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR" in lieu of "Keep Out of Reach of Children." This is acceptable under 40 CFR §156.66(c).
6. The companion animal safety study in MRID 42889006 was reviewed and classified as acceptable by HED (TXR 0010660; November 16, 1993) with the following comment:

Classification: ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

The proposed label for 2517-RAA includes the statement: "Do not use on puppies under 12 weeks." From PR Notice 96-6 a 12-week minimum age is acceptable ("The minimum age may not be less than 12 weeks unless accepted domestic animal safety data are on file at the Agency to support use on younger animals.").

7. TRB concludes that the acute toxicity and companion animal safety data requirements to support the registration of 2517-RAA have been satisfied by the data citations to MRIDs 42889001 through 42889006.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 18, 2013

Subject: Name of Pesticide Product: SPCP4
EPA Reg. No. /File Symbol: 2517-RAA
DP Barcode: DP 415945
Decision No.: 483206
Submission #: #941083
Action Code: R301
PC Code: 097805 (Deltamethrin: 4%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Nov-18-2013
JRK

To: Linda DeLuise/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

| | |
|------------------------------|---------------|
| <u>Active Ingredient(s):</u> | <u>by wt.</u> |
| 097805 Deltamethrin | 4.0% |
| <u>Inert Ingredients:</u> | 96.0% |
| TOTAL | 100.0% |

ACTION REQUESTED: The Risk Manager requests:

"Please screen for animal studies... Please screen this for deficiencies..."

BACKGROUND:

The material received for review includes a cover letter dated September 13, 2013; a transmittal document dated September 13, 2013; an application for pesticide registration indicating that this product is similar or identical in composition and labeling to EPA Reg. No. 68451-1, an 8-page

proposed label, a data matrix (which cites MRID 42889001 to satisfy the acute oral toxicity data requirement, 42889002 to satisfy the acute dermal toxicity requirement, an “N/A” for the acute inhalation toxicity study requirement; 42889003 to satisfy the primary eye irritation requirement; 42889004 to satisfy the primary dermal irritation requirement, 42889005 to satisfy the dermal sensitization requirement, and 42889006 to satisfy the companion animal safety study in dogs (870.7200) data requirement. In addition, there is a basic CSF and 3 alternate CSFs (all dated September 12, 2013).

COMMENTS AND RECOMMENDATIONS:

1. The registrant should formally request a waiver of the inhalation data requirement and give a reasonable argument as to why it should be waived (it would be sufficient to cite MRID 49211401).
2. After comparing the proposed basic and alternate CSFs, TRB concludes that the differences between them (including different sources of active and/or inert ingredients, presence or absence of fragrance) are not toxicologically significant.
3. After comparing the CSFs of 2517-RAA and the product cited as similar (EPA Reg. No. 68451-1) TRB concludes they are toxicologically similar.
4. The companion animal safety study in MRID 42889006 has been previously reviewed in HED (TXR 0010660, memorandum dated November 15, 1993 from John Doherty to George LaRocca) and classified as acceptable for adult dogs. From PR Notice 96-6: “The minimum age may not be less than 12 weeks unless accepted domestic animal safety data are on file in the Agency to support use on younger animals.” The last accepted (March 21, 2012) label for EPA Reg. No. 68451-1 includes the statement: “Do not use on puppies under 12 weeks” as does the proposed label for 2517-RAA.
5. TRB concludes that, with a waiver of the inhalation data requirement, the cited acute toxicity studies (MRIDs 42889001 through 42889005) and the cited companion animal safety study (MRID 42889006) adequately address the toxicological data requirements for the registration of 2517-RAA. The precautionary labeling of 2517-RAA should be consistent with that of the current label for 68451-1.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 415944; **FILE SYMBOL No.:** 2517-RAA; **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

DATE OUT: February 10, 2014

SUBJECT: End Use Product Chemistry Review
Product Name: SPCP4

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S. Mathur
02/10/14
JCR

TO: Linda DeLuise / Richard Gebken, RM 10
Herbicide Branch / RD (7505P)

Company Name: Seargent's Pet Care Products Incorporation
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application to register the new end use product SPCP4. The registrant has submitted CSF's for basic formulation and three alternate CSF's #1 to #3 (all dated September 12, 2013). The supporting product chemistry data have been submitted with MRID No's. 492107-01 and 492107-02. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 68451-1. TRB has been asked to determine the acceptability of the proposed basic& alternate CSF's and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Deltamethrin (4.0%)
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes, give the registration number of the cited product.

Reg. No. 68451-1

DP BARCODE No.: 415944; **FILE SYMBOL No.:** 2517-RAA; **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

3. All of the source materials of the active ingredient are derived from registered sources: ☒ Yes ☐ No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: ☐ Yes; ☒ No

Note: Three of the inert ingredients present in the formulations have not been cleared by the Agency. Additional information is needed with respect to their chemical composition.

5. Confidential Statement of Formula(s):

☒ Proposed Basic - Dated: 09-12-2013; Resubmitted – Dated:

☒ Proposed Alternate CSF #1 to #3 – All Dated: 09-12-2013; Resubmitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA;

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: 415944; **FILE SYMBOL No.:** 2517-RAA; **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

7. Group A: Product Chemistry Data

| Guideline No. | Study Title | | Data submitted | | TRB's Assessment of Data | MRID Nos. Cited |
|---------------|--|--------------------------------|----------------|----|--------------------------|----------------------|
| | | | Yes | No | | |
| 830.1550 | Product Identity & Composition | | X | | U | 492107-01 |
| 830.1600 | Description of materials used to produce the product | | X | | A | 492107-01 |
| 830.1650 | Description of formulation process | | X | | A | 492107-01 |
| 830.1670 | Discussion on the formation of impurities | | X | | A | 492107-01 |
| 830.1700 | Preliminary analysis | | | | | |
| 830.1750 | Certified limits (158.350) | Standard certified limits | X | | | Basic CSF (09-12-13) |
| | | Proposed Limits | | | | |
| | | Justification for wider limits | | | | |
| 830.1800 | Enforcement analytical method | | X | | A | 492107-03 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: 415944; **FILE SYMBOL No.:** 2517-RAA; **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

8. Group B:

| Guideline No. | Study Title | Value or Qualitative Description | TRB's Assessment of Data | MRID Nos. |
|---------------|---------------------------|---|--------------------------|-----------|
| 830.6303 | Physical State | Flexible PVC Solid | A | 492107-02 |
| 830.6314 | Oxidation/reduction | None | A | 492107-02 |
| 830.6315 | Flammability | NA | A | 492107-02 |
| 830.6316 | Explodability | NA | A | 492107-02 |
| 830.6317 | Storage stability | In progress. Will be submitted on completion | I | 492107-02 |
| 830.6320 | Corrosion characteristics | In progress. Will be submitted on completion | I | 492107-02 |
| 830.7000 | pH | NA. Test material is a solid and not dispersible in water | A | 492107-02 |
| 830.7100 | Viscosity | NA | | 492107-02 |
| 830.7300 | Density | 1.2455* g/ml @ 20°C | A | 492107-02 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress

*A one inch piece of collar was cut, measure and placed in a graduated cylinder containing water. Calculation was based on amount of water displaced by collar.

DP BARCODE No.: 415944; **FILE SYMBOL No.:** 2517-RAA; **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

C. CONCLUSIONS:

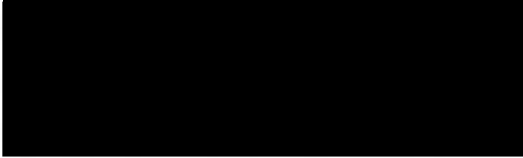
The TRB has reviewed the proposed basic & alternate CSF's and the supporting product chemistry data for the new end use product and has concluded:

1. The proposed CSF's for basic & alternate formulations (all dated 09-12-2013) are not acceptable. The CSF's contain three inert ingredients which are not cleared by the Agency. The registrant must provide additional information on the composition of three inert ingredients. For the names of the inert ingredients please refer to Confidential Appendix.
2. The product chemistry data submitted corresponding to the guideline 830 series group A are partially acceptable. See item #1.
3. The product chemistry data submitted for group B are acceptable. The registrant indicated that the studies for the guideline 830.6317 (1year storage stability) and 830.6320 (1 year corrosion characteristics) are in progress and the results will be submitted on completion.
4. The substantial similarity of the proposed product to the cited product will be determined after the receiving the additional information on the composition on the un-cleared inert ingredient and the approval of the proposed basic and alternate CSF's.

DP BARCODE No.: 415944; **FILE SYMBOL No.:** 2517-RAA; **PRODUCT NAME:** SPCP4; **DECISION No.:** 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** No

CONFIDENTIAL APPENDIX

Additional information on the composition of the following information is required:





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D415944; **FILE SYMBOL No.:** 2517-RAA (screen); **PRODUCT NAME:** SPCP4;
DECISION No.: 483206; **PC Code(s):** 097805; **ACTION CODE:** R301; **FOOD Use:** Yes

DATE OUT: December 19, 2013

SUBJECT: Completeness check screening for end use product "SPC4"

FROM: Shyam Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

SB Mathur
12/19/13

TO: Linda DeLuise / Deborah McCall, Branch Chief
Insecticide Branch / RD (7505P)

Company Name: Sergeant's Pet Care Products, Incorporation.

Formulation Type: Insecticide

Active Ingredient(s): Deltamethrin (4.0%)

Results of completeness check screen

| File No./ Reg. No | Product Name | Group A Data Submitted | | Group B Data Submitted | | CSF | | Label |
|----------------------|--------------|---------------------------|----|---------------------------|----|--|----|-------|
| | | Yes | No | Yes | No | Yes | No | |
| 2517-RAA | SPCP4 | + | | + | | + | | + |
| | | | | | | Basic & Alt #1, #2 #3 dated 9-12-13 | | |

CONCLUSION:

Group A: Data submitted

Group B: Submitted

CSF: Basic & Alt CSF's #1, #2 & #3 (all dated 09-12-13) submitted

Note: Few of the inert ingredients present in the formulations are not cleared by IIAB. Additional information is required on the composition of the number of inert ingredients used in basic & alternate CSF's.

MRID Nos. 492107-01 and 492107-02



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Data Matrix

| | | |
|--|---|--------------------|
| Date: February 11, 2014 | EPA Reg. No./File Symbol: 2517-RAA | Page 1 of 2 |
| Applicant's/Registrant's Name and Address: Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710 | Product Name: SPCP4 | |

Ingredients:

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Notes |
|----------------------------|----------------------|-------------|-----------|--------|-------|
|----------------------------|----------------------|-------------|-----------|--------|-------|

§ 158.310: Product Chemistry Data Requirements

| | | | | | |
|----------|--|----------|------------------------------------|-----|----------|
| 830.1550 | Product identity and composition | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1600 | Description of materials used to produce the product | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1620 | Description of production process | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1650 | Description of formulation process | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1670 | Discussion of formation of impurities | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1700 | Preliminary analysis | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1750 | Certified limits | 49210701 | Sergeant's Pet Care Products, Inc. | OWN | Volume 2 |
| 830.1800 | Enforcement analytical method | 49210703 | Sergeant's Pet Care Products, Inc. | OWN | Volume 4 |

Physical and Chemical Properties

| | | | | | |
|----------|---|----------|------------------------------------|-----|----------|
| 830.6302 | Color | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6303 | Physical state | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6304 | Odor | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6313 | Stability (normal/elevated temperatures, metals and ions) | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6314 | Oxidation/reduction: chemical incompatibility | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6315 | Flammability | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6316 | Explosibility | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6317 | Storage stability | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6319 | Miscibility | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6320 | Corrosion characteristics | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.6321 | Dielectric breakdown voltage | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.7000 | pH | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.7100 | Viscosity | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.7300 | Density/relative density/bulk density | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |
| 830.7520 | Particle size, fiber length and diameter distribution | 49210702 | Sergeant's Pet Care Products, Inc. | OWN | Volume 3 |

Signature:

Kelly R. Hoskins

Name and Title:

Kelly Hoskins
Director, Regulatory Affairs

Date:

Feb 11, 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Data Matrix

| | | |
|--|---|--------------------|
| Date: February 11, 2014 | EPA Reg. No./File Symbol: 2517-RAA | Page 2 of 2 |
| Applicant's/Registrant's Name and Address: Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710 | Product Name: SPCP4 | |

Ingredients:

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Notes |
|----------------------------|----------------------|-------------|-----------|--------|-------|
|----------------------------|----------------------|-------------|-----------|--------|-------|

§ 158.400: Product Performance Data Requirements

| | | | | | |
|----------|----------|----------|---------------|-----|--|
| 810.3300 | Efficacy | 44190101 | Intervet Inc. | OLD | |
| 810.3300 | Efficacy | 44578702 | Intervet Inc. | OLD | |
| 810.3300 | Efficacy | 44578703 | Intervet Inc. | OLD | |
| 810.3300 | Efficacy | 44578704 | Intervet Inc. | OLD | |
| 810.3300 | Efficacy | 44578705 | Intervet Inc. | OLD | |
| 810.3300 | Efficacy | 44602901 | Intervet Inc. | OLD | |

§ 158.500: Toxicology Data Requirements

| | | | | | |
|----------|---------------------------------------|----------|------------------------------------|-----|--|
| 870.1100 | Acute oral toxicity | 42889001 | Bayer Environmental Science | OLD | |
| 870.1200 | Acute dermal toxicity | 42889002 | Bayer Environmental Science | OLD | |
| 870.1300 | Acute inhalation toxicity | 49211401 | Sergeant's Pet Care Products, Inc. | OWN | |
| 870.2400 | Primary eye irritation | 42889003 | Bayer Environmental Science | OLD | |
| 870.2500 | Primary dermal irritation | 42889004 | Bayer Environmental Science | OLD | |
| 870.2600 | Dermal sensitization | 42889005 | Bayer Environmental Science | OLD | |
| 870.7200 | Companion animal safety study in dogs | 42889006 | Bayer Environmental Science | OLD | |

§ 158.1070: Post-Application Exposure Data Requirements

| | | | | | |
|----------|--------------------------|----------|------------------------------------|-----|--|
| 875.2300 | Pet transferable residue | 48589901 | Sergeant's Pet Care Products, Inc. | OWN | |
|----------|--------------------------|----------|------------------------------------|-----|--|

Signature:

Kelly R. Hoskins

Name and Title:

Kelly Hoskins
Director, Regulatory Affairs

Date:

Feb 11, 2014

Attention PM Team:

For additional CSFs,
please check in earlier
volumes including
imaged volumes.

Basic & Alt 1-3 approved → all dated 3/26/14
in Imaged e-jacket